UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MISSOURI
EASTERN DIVISION

MONSANTO COMPANY,	)	
	)	
Plaintiff,	)	
	)	
vs.	)	Case No. 4:00CV01915 ERW
	)	
BAYER BIOSCIENCE N.V.,	)	
	)	
Defendant.	)	

MEMORANDUM AND ORDER

This matter comes before the Court upon Defendant's Motion for Summary Judgment [doc. #496]. On December 4, 2000, Monsanto Company [Monsanto] filed suit against Bayer Bioscience N.V. [Bayer] seeking a declaratory judgment that Monsanto's MON810 product, also known as YieldGuard, does not infringe on certain patents owned by Bayer. Monsanto also seeks a declaratory judgment that Bayer's patent claims are invalid and unenforceable. In a separate ruling entered on this date on Defendant's Motion for Summary Judgment [doc. # 490], the Court declared Claims 1, 7 and 12 invalid, so that the only patent claims that remain in issue are Claims 2, 5, and 8 of Bayer's United States Patent 5,545,565 [the '565 patent].[1] Defendant seeks partial summary judgment indicating that Monsanto's defense of prior inventorship does not meet the

[1]The claims still in issue are 2, 5, and 8. The claims are as follows:
2. The chimeric gene as defined in claim 1, wherein said Bt2 toxin comprises the amino acid sequence of SEQ ID No. 1 from amino acid position 1 to an amino acid position between amino acid position 607 and amino acid position 725.
5. The chimeric gene as defined in claim 1, wherein said Bt2 toxin comprises the amino acid sequence of SEQ ID No. 1 from amino acid position 1 to amino acid position 725.
8. The chimeric gene as defined in any of claims 2 to 6, wherein said DNA fragment is artificially made.

requirements of 35 U.S.C. § 102(g) and must fail as a matter of law. For the reasons below, the motion is denied.

I. BACKGROUND

The '565 patent application was filed on January 22, 1986. The patent claims specify an invention of a "chimeric gene[2]. . . encoding Bt2 toxin. . ., wherein said Bt2 toxin comprises the amino acid sequence of SEQ ID No. 1[.]" The amino acid sequence of SEQ ID No. 1 is identified in the '565 patent. SEQ ID No. 1 is the name given to describe the disclosed 4014 base pairs of nucleotides encoding the amino acid sequence of the Bt2 gene. The patent also discloses one of the DNA sequences that will encode the amino acid sequence described as SEQ ID No. 1.

Prior to the date of Bayer's patent application, Dr. David Fischhoff, a scientist at Monsanto, worked to isolate and sequence a truncated Bt gene. Monsanto claims that, by October 25, 1984, Dr. Fischhoff had a definite and permanent idea to create a chimeric gene comprising a DNA fragment encoding the first 725 amino acids of Monsanto's CryIA(b) protein, a promoter and a 3' non-translated region. By January 22, 1986, Dr. Fischhoff had isolated the DNA.[3] He had created a restriction map, called the pMap1202.[4] He had characterized the length of the gene needed to encode the active portion of the Bt protein. He had sequenced both ends of the gene. He had also deposited the DNA in a public depository to support his own patent application.[5] Furthermore, by the January 22, 1986 priority date of Bayer's application, Monsanto scientists had obtained a sequence that was 98.6% identical to the final protein sequence determined in April 1986. However, Dr. Fischhoff and other scientists at Monsanto did

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[2]A "chimeric gene" is comprised of parts that do not occur in nature together. The insecticidal Bt2 protein does not naturally occur in a plant's DNA.

[3]Monsanto had isolated the gene by 1983.

[4] The restriction map was created no later than April 15, 1985. Restriction maps help identify where to "cut" the DNA.

[5]The deposit was made in December 1984.

not determine the complete gene and amino acid sequences of the Bt toxin at issue in this case until around April 22, 1986.

II. SUMMARY JUDGMENT STANDARD

Pursuant to Federal Rule of Civil Procedure 56(c), a court may grant a motion for summary judgment only if all of the information before the court shows "there is no genuine issue of material fact and the moving party is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(c); Crumley v. City of St. Paul, 324 F.3d 1003, 1006 (8th Cir. 2003). The United States Supreme Court has noted that "[s]ummary judgment procedure is properly regarded not as a disfavored procedural shortcut, but rather as an integral part of the federal rules as a whole, which are designed to 'secure the just, speedy and inexpensive determination of every action.'" Celotex Corp. v. Catrett, 477 U.S. 317, 322 (1986) (quoting Fed. R. Civ. P. 1).

"'By its terms, [Rule 56(c)(1)] provides that the mere existence of *some* alleged factual dispute between the parties will not defeat an otherwise properly supported motion for judgment; the requirement is that there be no *genuine* issue of *material* fact.'" Hufsmith v. Weaver, 817 F.2d 455, 460 n.7 (8th Cir. 1987) (quoting Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 247-48 (1986) (emphasis added by Supreme Court)). Material facts are "those 'that might affect the outcome of the suit under governing law.'" Id. (quoting Anderson, 477 U.S. at 247-48). Summary judgment will be denied due to a material issue of genuine fact if "the evidence is sufficient to allow a reasonable jury to return a verdict for the non-moving party." Crumley, 324 F.3d at 1006. Further, if the non-moving party has failed to "make a showing sufficient to establish the existence of an element essential to that party's case, . . . there can be 'no genuine issue as to any material fact,' since a complete failure of proof concerning an essential element of the nonmoving party's case necessarily renders all other facts immaterial." Celotex, 477 U.S. at 322-23, quoted in St. Jude Med., Inc. v. Lifecare Intern., Inc., 250 F.3d 587, 595 (8th Cir. 2001).

The initial burden of proof in a motion for summary judgment is placed on the moving party to establish the non-existence of any genuine issue of fact that is material to a judgment in its favor. Crumley, 324 F.3d at 1006 (citing Lynn v. Deaconess Med. Ctr.-W. Campus, 160 F.3d 484, 487 (8th Cir. 1998)). The burden then shifts to the non-moving party who must set forth specific evidence showing that there is a genuine dispute as to material issues. Anderson, 477 U.S. at 249. To meet its burden, the non-moving party may not rest on the pleadings alone and must "do more than simply show there is some metaphysical doubt as to the material facts." Matsushita, 475 U.S. at 586.

In analyzing summary judgment motions, the court must view the evidence in the light most favorable to the non-moving party. Crumley, 324 F.3d at 1008. The non-moving party is given the benefit of any inferences that can logically be drawn from those facts. Matsushita, 475 U.S. at 586. The court may not "weigh the evidence in the summary judgment record, decide credibility questions, or determine the truth of any factual issue." Kampouris v. St. Louis Symphony Soc., 210 F.3d 845, 847 (8th Cir. 2000). The court instead "perform[s] only a gatekeeper function of determining whether there is evidence in the summary judgment record generating a genuine issue of material fact for trial on each essential element of a claim." Id.

III. DISCUSSION

Monsanto argues that the '565 patent is invalid because scientists at Monsanto allegedly invented the chimeric gene at issue in this case before Bayer. 35 U.S.C. Section 102(g)(2) indicates that an applicant will not receive a patent if

> before such person's invention thereof, the invention was made in this country by another inventor who had not abandoned, suppressed, or concealed it. In determining priority of invention under this subsection, there shall be considered not only the respective dates of conception and reduction to practice of the invention, but also the reasonable diligence of one who was first to conceive and last to reduce to practice, from a time prior to conception by the other.

Conception is a question of law predicated on underlying factual findings. Singh v. Brake, 317 F.3d 1334, 1340 (Fed. Cir. 2003). If a person fails to reduce to practice the invention before another person has filed a patent application for the same invention, the person that failed to reduce to practice the invention may still be a prior inventor if he had "conception" of the invention before the patent applicant and used reasonable diligence to reduce the invention to practice. In this case, the Court will assume that Bayer's invention was reduced to practice on January 22, 1986, the same day Bayer filed its U.S. patent application serial number 06/821,582. However, Monsanto argues that even though the chimeric gene was reduced to practice by Monsanto scientists after Bayer had filed its patent application, Monsanto scientists had conception of the truncated Bt2 gene prior to Bayer's date of invention and diligently reduced to practice the invention. Monsanto must show by clear and convincing evidence that its scientists had conception of the gene prior to Bayer filing the '565 patent application in order to be considered the prior inventor of the Bt2 chimeric gene. See Mycogen Plant Science v. Monsanto Co., 243 F.3d 1316, 1332 (Fed. Cir. 2001).

"Conception is the formation in the mind of the inventor of a definite and permanent idea of the complete and operative invention, as it is therefore to be applied in practice." Singh, 317 F.3d at 1340 (quoting Kridl v. McCormick, 105 F.3d 1446, 1449 (Fed.Cir.1997)) (internal citations omitted). "A conception must encompass all limitations of the claimed invention, and is complete only when the idea is so clearly defined in the inventor's mind that only ordinary skill would be necessary to reduce the invention to practice, without extensive research or experimentation." Id. (internal citations omitted); Hitzeman v. Rutter, 243 F.3d 1345, 1354 (Fed. Cir. 2001). "The conception analysis necessarily turns on the inventor's ability to describe his invention with particularity. Until he can do so, he cannot prove possession of the complete mental picture of the invention." Burroughs Wellcome Co. v. Barr Labs., Inc., 40 F.3d 1223, 1228 (Fed. Cir. 1994).

Bayer correctly recognizes that this motion for partial summary judgment can be narrowed to the following issue: if a claim specifically recites a DNA fragment encoding a specified amino acid sequence, does the law require knowledge by Monsanto of either the complete DNA sequence or the complete amino acid sequence or the complete DNA fragment encoding that sequence for there to be conception of the claimed invention?

"A gene is a chemical compound, albeit a complex one, and it is well established in our law that conception of a chemical compound requires that the inventor be able to define it so as to distinguish it from other materials[.]" Amgen, Inc. v. Chugai Pharm. Co., Ltd., 927 F.2d 1200, 1206 (Fed. Cir. 1991). Conception occurs when "one has a mental picture of the structure of the chemical, or is able to define it by its method of preparation, its physical or chemical properties, or whatever characteristics sufficiently distinguish it." In re Wallach, 378 F.3d 1330, 1335 (Fed. Cir. 2004). In prior cases and interference proceedings, it has consistently been held that until an inventor knows both the nucleotide sequence of a DNA fragment and an operative method of isolating that fragment, the idea is inadequate to constitute conception.[6] Chiron Corp. v. Abbott Labs., 902 F.Supp. 1103, 1120-21 (N.D. Cal. 1995). See also Burroughs Wellcome, 40 F.3d at 1229; Fiers v. Revel, 984 F.2d 1164, 1168-69 (Fed. Cir. 1993); Colbert v. Lofdahl, 21 U.S.P.Q.2d 1068, 1071 (P.T.O. Bd.Pat.App. & Int. 1991); Fritsch v. Lin, 21 U.S.P.Q.2d 1731, 1734 (P.T.O. Bd.Pat.App. & Int. 1991); and Amgen, Inc., 927 F.2d at 1207.

[6]Specifically, the Court held that restriction maps alone are insufficient to determine the sequence of nucleotides in a gene. The court found that "[w]hile restriction maps enable scientists to identify and 'cut' specific fragments of DNA, 'sequencing' is more precise, and enables scientists to create a complete map of the exact order of the nucleotides comprising the DNA." Chiron Corp., 902 F.Supp. at 1108. In Colbert v. Lofdahl, the Court does say that "conception has not been achieved until reduction to practice has occurred, i.e., until after the gene has been isolated." 21 U.S.P.Q.2d at 1071. However, in the next sentence, the Court indicates that the inventor would only know the "complex chemical compound" if the "DNA molecule had been isolated and its nucleotide sequence known." Id. As a whole, the opinion clearly held that conception required both knowledge of the nucleotide sequence and the isolation of the gene.

The factual circumstances relating to Dr. Fischhoff's work with the Bt gene alleged to infringe on the '565 patent are quite different than the facts in the cases cited by Bayer. For example, in Chiron v. Abbott Laboratories, the party claiming it was the prior inventor had only described restriction sites of the DNA fragment. 902 F.Supp. at 1120. The party had not isolated the fragment or determined any part of the nucleotide sequence of the fragment. Id. Furthermore, the inventor could not be sure the desired protein had been expressed without the complete nucleotide sequence. Id. at 1121.

In Colbert v. Lofdahl, the party claiming to be the prior inventor of a gene did not have prior conception of the gene encoding a certain "protein A" just because it had positive tests in an assay testing for protein A activity. 21 U.S.P.Q.2d at 1071. The gene had not been isolated, and the nucleotide sequence was unknown. Id. The court held that the party did not have adequate knowledge of the chemical structure of the gene and, thus, did not have conception of the gene. Id.

In Amgen v. Chugai Pharmaceutical, the putative inventor had not even isolated the gene. 927 F.2d at 1207. Expert testimony indicated that success in cloning the particular gene in issue in the case required that the gene be isolated and its nucleotide sequence known. Id.

The supposed inventor in In re Wallach had isolated the gene but had only sequenced 5% of the protein. 378 F.3d at 1333. The only disclosed function of the DNA was to encode the particular protein. The court held that, while it is true that "a protein's amino acid sequence is an inherent property of the protein," isolation and physical possession of the gene "does not amount to knowledge of that protein's sequence or possession of any of its other descriptive properties." Id. at 1334-35. The court held that until an inventor obtains the complete amino acid sequence of a protein, one does not have "more than a wish to know the identity of the DNA encoding it." Id. at 1335. However, the court's reasoning was based on, inter alia, the fact that no evidence was

introduced that "the full amino acid sequence of a protein can be deduced from a partial sequence and the limited additional physical characteristics that they have identified." Id.

The evidence presented by Monsanto demonstrates that Dr. Fischhoff and the other Monsanto scientists knew much more about the Bt gene fragment than those supposed prior inventors in the cases cited by the parties. Monsanto had isolated the gene three years before Bayer filed its patent application. Monsanto had accurately sequenced both the 3' and 5' ends of the Bt gene fragment. Dr. Fischhoff had created the pMap1202 with restriction sites. Monsanto had deposited a sample of the DNA in a public depository. Also, prior to the critical date, Monsanto had estimated the sequence for the Bt gene fragment, and that estimate was 98.6% identical to the final sequence determined in April 1986.

In other cases, such as Chiron, courts have found that without knowledge of the nucleotide sequence, the scientist would not know if the right protein was expressed. Unlike those cases, Monsanto has presented evidence that knowledge of the nucleotide sequence was unnecessary so long as the plant expressed the desired insecticidal toxin. Finally, the most significant difference between this case and prior cases is that Monsanto has presented evidence to the Court, from an expert in the field, that sequencing the remaining 3% of the DNA sequence would have been "routine" at the time, and that the amino acid sequence could be readily deduced from Monsanto's deposited gene by those of ordinary skill in the art. For these reasons, the Court finds that there is a genuine issue of material fact as to whether Monsanto was a prior inventor of the Bt gene fragment at issue in this case.[7] The genuine issue relates to whether Monsanto had knowledge of the chemical structure of the Bt gene fragment to such an extent that the fragment could adequately be distinguished from other chemical compounds. The material facts in dispute

[7]The Court finds it is unnecessary, at this time, to address Monsanto's arguments that (1) the DNA sequence is inherent in the compound itself and (2) the claims of the '565 patent are not novel because the Bt2 gene was not "new." See In re Crish, 393 F.3d 1253 (Fed. Cir. 2004).

relate to the evidence presented by Monsanto that (1) knowledge of the Bt2 sequence was not needed to make the claimed chimeric gene once Monsanto scientists had isolated the gene, identified the toxic fragment, and sequenced the ends of the gene to facilitate manipulation, and (2) sequencing the Bt2 DNA fragment was something that was well within the capability of someone of ordinary skill in the art as of October 1984 once the fragment had been isolated and identified.

Accordingly,

IT IS HEREBY ORDERED that Defendant's Motion for Partial Summary Judgment Dismissing Monsanto's Defenses Under 35 U.S.C. Section 102 [doc. # 496] is **DENIED**.

Dated this 10th day of May, 2005.

E. RICHARD WEBBER
UNITED STATES DISTRICT JUDGE